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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,897	01/30/2004	Robert S. Coffin	117-489	5701

23117 7590 10/04/2005

NIXON & VANDERHYE, PC
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ARLINGTON, VA 22203

EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,897

Applicant(s)

COFFIN, ROBERT S.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/30/04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

In the request for a corrected filing receipt filed 6/21/2004, applicant incorrectly stated the filing date of application 09/744,942. The filing date of an application under 35 USC 371 is the date that all U.S. filing requirements are completed, not the date that the application is transmitted. The required inventor's oath or declaration was filed 8/6/2001, so that is the U.S. national filing date. The first paragraph of the specification should be amended to include the 8/6/2001 filing date for 09/744942.

Claim Rejections - 35 USC § 112

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-16 require "administering to a subject... an attenuated herpesvirus... such that dendritic cells are infected with said virus." After reading the specification, it is not clear what is involved in "administration...such that dendritic cells are infected with said virus." The specification states on page 2 that herpes simplex viruses effectively infect and deliver genes to dendritic cells, but it is not clear if this statement refers to in vitro or in vivo infection. The detailed guidance for administration of the virus on pages 16-17 discusses administration of the virus to induce an immune response, but does not clearly address how to administer the virus to infect dendritic cells in vivo. The last paragraph on page 17 merely states to administer the virus in such a way that the virus can infect dendritic cells, and discusses amounts of virus, then discusses intra-dermal or trans-dermal administration. Nowhere does the

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specification give clear guidance on whether any particular means of administration are required to produce "such a way that the virus can infect dendritic cells" in a human or animal subject. Since it is not clear what form of administration is involved in the method, the public is not reasonably apprised of the scope of the claimed invention, and it is concluded that the claims are indefinite.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method involving ex vivo infection of dendritic cells, does not reasonably provide enablement for in vivo infection of dendritic cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Claims 1-16 involve administering to a subject an effective amount of an attenuated herpes virus such that dendritic cells are infected with the virus. The specification teaches that dendritic cells can be infected with herpesviruses in vitro, and the prior art recognizes methods of administering ex vivo modified dendritic cells. However, the specification provides no teachings how to administer a virus to a subject in such a way that the subject's dendritic cells become infected with the virus. The specification suggests administering a herpesvirus intradermal or transdermally (page 17), but provides no evidence that such administration actually produces infected dendritic cells. Those skilled in the art would be aware of routine methods of administering a herpesvirus to a subject in a manner effective to obtain an immune response, or in a manner effective to achieve expression of a foreign gene. However, the invention as claimed specifically requires infection of dendritic cells, and there is

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nothing in the prior art of record or in the specification which indicates that routine methods of administering herpesviruses will result in infection of dendritic cells.

Considering the very limited teachings in the specification, the lack of any working example, and the absence of knowledge in the prior art as to methods for infecting dendritic cells in vivo, it is concluded that undue experimentation would be required to practice the full scope of the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krisky et al (Gene Therapy 5:1517-1530, 1998) or Glorioso et al (US 5998174). Both references teach recombinant herpes vector viruses which have defective vhs (UL41) and ICP47 genes and functional UL43 genes. See the HX86 series of constructs. The references differ from the claimed invention in that they do not administer the viruses to a subject in a manner such that dendritic cells are infected with the virus. However, both references explicitly suggest using the viruses to stimulate immune responses. If routine methods of administering the virus are sufficient to cause infection of dendritic cells, then carrying out the explicit suggestion according to routine methods would result in the same process as claimed. Therefore the invention as a whole is seen as prima facie obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6713067. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass the previously patented subject matter.

Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over at least claims 1-19 of copending Application No. 10/273348. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/30/05


MARY E. MOSHER, PH.D.
PRIMARY EXAMINER